

**K960315 FLAVORED LATEX PATIENT EXAMINATION**Nov 20, 1996  
302 days to decision

K960315 · Product code: LYY · General Hospital

Source: <https://www.510kdatabase.net/k960315/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jan 23, 1996
Decision date	Nov 20, 1996
Days to decision	302 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>P.T. Irama Dinamika Latex</b>
Location	Medan - Indonesia, ID
Contact	ANIL TANEJA
510(k) history	11 submissions · 11 cleared · 1991-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k960315/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 5, 2026